AUG 1 2000 K002085

510(k) Summary:

This summary is provided as part of this Premarket Notification in compliance with 21CRF, Section 807.92.

Submitters name: B-K Medical A/S
Address: Sandtoften9, DK2820Gentofte, Denmark
Phone: +45 45970100
Fax: +45 45970199
Contact person: Villy Braender, Quality Assurance Mnager
Date prepared: 5.July, 2000

Trade name: Ultrasound Scanner Type 1101
Common name: Diagnostic Ultrasound System
Classification names:

Ultrasonic Pulsed Echo Imaging System	(90 IYO, CFR 892.1560)
Diagnostic Ultrasonic Transducer	(90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device:
B-K Medical A/S 2002 Ultrasound Scanner (K943315)

Device description:

1101 supports the following scanning modes and combinations thereof:
B-mode M-mode.
The system can perform simple geometric measurements, and perform calculations in the areas of Vascular, Urology, Cardiology and OB/GYN applications.
The system can guide biopsy- and puncture needles.

Transducers
Transducers are linear and convex array and mechanical sector.
The patient contact materials comply with ISO10993-1
All transducers used together with 1101 are Track 3 transducers.

Acoustic output
The system controlling the Acoustic Output in 1101 is the same as the system in 2002. The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. Ispta $\leq$ 720 mW/cm^2 and MI $\leq$ 1.9 (Track 3, non ophthalmic).
The Thermal Index values are maximum 6.0, i.e. TI $\leq$ 6.0

Clinical measurement accuracy.
Clinical measurements and calculations are described and accuracies are provided in the User Guide.

Thermal, mechanical and electrical safety.
The scanner 1101 is tested by a recognized, certified body according to IEC 60601-1 .

Acoustic Output Reporting
The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 30, 1997"

The acoustic output is measured and calculated according to: "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (NEMA 1997).

Intended use.
1101 intended uses are contained within 2002-intended uses:

	Predicate device, Ultrasound scanner Type 2002 (K943315)	Submitted device, Ultrasound scanner Type 1101
Modes of operation	B, M, PWD, CFM and combinations	B, M and combinations
Intended use(clinical application)	Abdominal Cardiac Fetal Doppler Intraoperative Neurosurgery Obstetrics Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular	Abdominal Cardiac Fetal Intraoperative Neurosurgery Obstetrics Pediatrics Transrectal Small Parts (organs) Transvaginal

Technological characteristics compared to the predicate device.
The predicate device has the same major technological characteristics as the subject device described above.
Minor differences consist: The subject device has modified transmitter, increased beamformer delay accuracy, increased storage capability and modified user interface and mechanical outline.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2000

Villy Braender
Official Correspondent
B-K Medical
Sandtoften 9
DK 2820 Gentofte,
Denmark

Re: K002085
Ultrasound Scanner Type 1101
Regulatory Class: II
21CFR 892.1560/Procode: 90 IYO
21CFR 892.1570/Procode: 90 ITX
Dated: July 5, 2000
Received: July 10, 2000

Dear Mr. Braender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Ultrasound Scanner Type 1101, as described in your premarket notification:

Transducer Model Number

1850
8556
8560
8561
8562
8565

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Diagnostic Ultrasound Indications for Use Form

System: 1101

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		X	X						X (B+M)	
Abdominal		X	X						X (B+M)	
Intraoperative (specify)		X	X						X (B+M)	
Intraoperative Neurological		X	X						X (B+M)	
Pediatric		X	X						X (B+M)	
Small Organ (specify)		X	X						X (B+M)	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		X	X						X (B+M)	
Transesophageal										
Transrectal		X	X						X (B+M)	
Transvaginal		X	X						X (B+M)	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001085

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 1101
Transducer: 1850

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	P						
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA(K943315); E= added under ~~Appendix~~ E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Intraoperative: Rectum, Urethra, Urinary bladder,_____-

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002085

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 1101
Transducer: 8556

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P	P				P (B+M)	
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA(K943315); E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David G. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002085

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 1101
Transducer: 8560

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	E	E				E (B+M)	
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	E	E				E (B+M)	
	Small Organ (Specify)	E	E				E (B+M)	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added (K943315) under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Intraoperative: Breast, liver, pancreas, biliary system
Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002085

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 1101

Transducer: 8561

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E				E (B+M)	
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	E	E				E (B+M)	
	Trans-vaginal	E	E				E (B+M)	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added (K943315) under Appendix E

*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments:

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002085

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 1101
Transducer: 8562

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	E	E				E (B+M)	
	Intra-operative (Neuro)	E	E				E (B+M)	
	Laparoscopic							
	Pediatric	E	E				E (B+M)	
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added (K943315) under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Intraoperative: Gall bla dder

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David A. Seyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002085

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 1101
Transducer: 8565

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E				E (B+M)	
	Abdominal	E	E				E (B+M)	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added (K943315) under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David A. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003085